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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Weenna Bucay-Couto

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

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05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,231	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2009 has been entered.
2. Claims 1-29 are currently pending, with claims 24-29 withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 21 recites the limitation "chemically crosslinking said crosslinkable *polymers*" in line 5. There is insufficient antecedent basis for this limitation in the claim. The claim previously recites "a crosslinkable polymer" in lines 3-4.

Claim Rejections - 35 USC § 102/103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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6. Claims 1-9, 11-14, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weikel et al. (US 6,632,235) in view of Trieu (US 2004/0186471). Regarding claim 1, Weikel et al. disclose a method of providing a solid polymeric body within a subject comprising injecting a fluid comprising a crosslinkable polymer into a container (30) that is positioned within the subject, chemically crosslinking the crosslinkable polymer in the container by introducing a chemical crosslinking agent to the container, thereby forming a crosslinked solid polymeric body in the container, and releasing the crosslinked solid polymeric body into the subject (col 6, ll 5-13; col 10, ll 58-61; col 11, ll 27-37). Weikel et al. disclose the filler material, which is injected into the container, may comprise a polymer that hardens or solidifies within the container before the container is removed (col 6, ll 5-13; col 10, ll 58-61; col 11, ll 27-37). Thus, inherently a chemical crosslinking agent is introduced into the container to crosslink and thereby solidify the polymer. Alternatively, it would have been obvious to introduce a chemical crosslinking agent into the container to form a chemically crosslinked solid polymeric body in the container. Trieu teaches a similar method of providing a solid polymeric body within a subject and teaches "it is preferred that the biomaterial can undergo transition from a flowable to non-flowable state shortly after injection. This can typically be achieved by adding a crosslinking agent to the biomaterial before, during, or after injection" (¶2004/0186471). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Weikel et al. to include the step of

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introducing a chemical crosslinking agent to the container to ensure the polymer is able to properly crosslink and solidify.

Regarding claims 2-5, the container is an expandable balloon, which may have elastic or inelastic walls (col 1, ll 58-60).

Regarding claim 6, the container is removed from the subject subsequent to releasing the crosslinked solid polymeric body (col 7, ll 16-25).

Regarding claims 7 and 8, the container is released within the patient along with the crosslinked solid polymeric body and the container is biodegradable (col 7, ll 26-43).

Regarding claim 9, the crosslinked solid polymeric body is biodegradable (col 10, ll 58-61).

Regarding claims 11-13, the crosslinked solid polymeric body is formed within a surgically created bodily lumen, or bodily cavity, of the subject (Figs 36-37).

Regarding claim 14, the crosslinked solid polymeric body may be considered an antiadhesive body, since in one embodiment the crosslinked solid polymeric body comprises a hydrogel (col 10, ll 58-61).

Regarding claims 16 and 18, the crosslinked solid polymeric body may be considered an embolic body or bulking agent since it takes up space within a body cavity.

Regarding claim 19, the crosslinked solid polymeric body may be considered a tissue scaffold.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weikel et al. (US 6,632,235) and Trieu (US 2004/0186471), as applied to claim 1 above, in view of Spacek (US 6,524,327). Weikel et al. and Trieu disclose the invention substantially as claimed as shown above. However, they do not disclose the method comprises washing the crosslinked polymeric body prior to releasing the crosslinked solid polymeric body. Spacek discloses a method for forming a solid polymeric body in situ and teaches once the crosslinking, or bonding, is complete, the polymeric body should be washed to remove unreacted reactants and any byproducts to ensure biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Weikel or the combination of Weikel and Trieu such that the step of washing the solid polymeric body was added to remove byproducts and reactants that may harm the body.

9. Claims 15, 17, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikel et al. (US 6,632,235) and Trieu (US 2004/0186471), as applied to claim 1 above, in view of Schwartz et al. (US 2005/0008610). Weikel et al. and Trieu disclose the invention substantially as claimed as shown above. However, regarding claims 15 and 17, they do not disclose the crosslinked solid polymeric body is used to occlude an aneurysm or a uterine fibroid tumor. Schwartz et al. discloses a

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similar method for forming a solid polymeric body in situ comprising injecting a fluid crosslinkable polymer and crosslinking the polymer within the body. Schwartz et al. teach the solid polymer may be used in a method to temporarily embolize a vascular site. "Embolization is a process wherein a material is injected into a blood vessel to at least partially fill or plug the vessel and/or encourage clot formation so that blood flow through the vessel is reduced or stopped. See Background of the Invention.

Embolization of a blood vessel can be useful for a variety of medical reasons, including preventing or controlling bleeding due to lesions (e.g., organ bleeding, gastrointestinal bleeding, vascular bleeding, and bleeding associated with an aneurysm), or to ablate diseased tissue (e.g., tumors, vascular malformations, hemorrhagic processes) by cutting off blood supply. Embolization may also be used to prevent blood loss during or immediately following surgery. Embolization of tumors may be performed preoperatively to shrink tumor size; to aid in the visualization of a tumor; and to minimize or prevent blood loss related to surgical procedures" (¶0082). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Weikel or the combination of Weikel and Trieu such that the polymeric body is formed within an aneurysm or disposed within an artery of a uterine fibroid tumor to cut off the blood flow to the aneurysm or tumor, respectively.

Regarding claim 20, Weikel et al. and Trieu do not disclose the crosslinked solid polymeric body further comprises a therapeutic agent. Schwartz et al. teach it is advantageous to include therapeutic agents in the polymeric body to deliver drugs at the right time, in a controlled manner, with minimal side effects, and greater efficacy per

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dose to help treat the target site where the embolic polymeric body is placed. The therapeutic agent may comprise an antiangiogenic agent to promote embolization (¶0068, 0109, 0112). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Weikel or the combination of Weikel and Trieu such that the crosslinked solid polymeric body further comprises a therapeutic agent to deliver the drug in a controlled manner at the site of action.

Regarding claims 21-23, Weikel et al. and Trieu do not disclose an additional crosslinkable polymer. However, it is well known in the art to compose solid polymeric bodies placed inside the body from multiple polymeric materials. Schwartz et al. disclose the solid polymeric body may be formed from a block copolymer comprising at least first, second, and third crosslinkable polymers (¶0068-0080). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Weikel or the combination of Weikel and Trieu such that the crosslinked solid polymeric body was formed of at least three crosslinkable polymers to incorporate desired properties from the additional polymer.

Response to Arguments

10. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
May 8, 2009

/K. M. D./
Examiner, Art Unit 3734